AUG 2 9 2002

K021916

Harmac
MEDICAL PRODUCTS, INC.

2201 Bailey Avenue • Buffalo, NY, U.S.A. 14211-1797
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510(k) Summary

This summary is submitted in support of the Harmac Huber Needle Safety Device and in conformance with the format described in 21 CFR Part 807.92 last revised on April 1, 2001.

1. **Date Submitted:**

   24 May 2002

   Submitted By:

   Harmac Medical Products, Inc.
   2201 Bailey Avenue
   Buffalo, NY 14211

   Contact Person:

   Christopher Izzo
   Sr. QA/RA Engineer
   (716) 897-4500 ext. 301 – voice
   (716) 893-8395 – fax
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2. **Name of Device:**

   Harmac Huber Needle Safety Device

   Classification Name:

   IV Administration Set/Accessory

3. **Identification of Predicate Devices:**

   510(k) Number: K950895
   Trade Name: Huber Needle Infusion Set
   Regulatory Class: II
   Product Code: FPA
   Harmac Medical Products, Inc.

   510(k) Number: K973497
   Trade Name: Huberloc
   Regulatory Class: Unclassified
   Product Code: LJT
   MedCare Medical Group, Inc.

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4. Description of Device Subject to Premarket Notification:

The Harmac Medical Huber Needle Safety Device is designed as an accessory to Harmac Huber Needle Infusion Sets to assist in the removal and containment of ninety-degree Huber needles from implanted IV ports. The device consists of a single injection molded plastic component incorporating a stabilizing foot and an internal design to capture the proprietary needle hub of the Harmac Medical Infusion Set as it is slid up a receiving slot in one side. Only one version of the device will be marketed and will accommodate a range of Harmac Huber needles up to 19 gauge, 1-1/2" in length.

The Huber Needle Safety Device is used by placing the open slot over the hub of the Harmac Infusion Set needle and using the foot of the device to stabilize the patient's skin via downward pressure with one hand. The other hand is used to grasp the wings of the Huber needle and draw it upward into the Safety Device. As the Huber needle reaches the top of the device the proprietary head locks into place. As the needle is drawn upwards it is also turned slightly to the side to keep the needle from protruding through the receiving slot.

This method of operation requires two hands but eliminates the rebound reflex by locking the needle hub and keeping the other hand behind the device at all times.

The Huber Needle Safety Device is provided as a sterile accessory packaged only with Harmac Infusion Sets. It is provided as a disposable, single use device.

5. Intended Use of the Device:

The intended use of this device is for the removal of 90 degree winged infusion sets, manufactured by Harmac Medical Products and having a 1-1/2" needle or shorter, from implanted ports and the containment of the used needle until placed in an appropriate sharps container. When used in this manner this device is intended to aid in the prevention of needle stick injuries.

6. Comparison to Predicate Device

The technological characteristics of the Harmac Huber Needle Safety device are the same as the predicate device(s) designated in section 3, above, as illustrated in the table below:

	"New" Harmac Device	Huberloc
Design	Compatible with 90-degree winged Huber needles up to 19 gauge, 1-1/2" length.	Compatible with 90-degree winged Huber needles up to 19 gauge, 1-1/2" length.
Material	One piece, made of Polystyrene plastic	Three pieces, made of Polystyrene plastic
How Provided	Sterile, single-use, disposable	Sterile, single-use, disposable

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Energy Source	Mechanical, provided by user	Mechanical, provided by user
Safety	Removed needle locked in place for disposal	Removed needle locked in place for disposal

7. Device Testing

The device underwent both bench testing and simulated clinical studies during the design control phase at Harmac according to the guidance in "Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features" published by the General Hospital Devices Branch in March 1995.

Bench studies using an Instron tester to simulate use demonstrated that the average force to engage the safety device was 2.91 lbs. and the average force to disengage the safety device was 15.51 lbs. The separation of these forces by more than six standard deviations gives a high confidence level that accidental disengagement is extremely unlikely to occur. Also, this study demonstrated that the design and material characteristics of the device are adequate to withstand the required forces during use.

Simulated clinical studies were performed with health care professionals familiar with the intended use of the device as well as the predicate device. Health care professionals received in-service training and filled out a detailed evaluation form during the study. Over 480 safety devices were tested on port trainers with NO (0) needle stick injuries and NO (0) significant problems with the safety feature that may have lead to an injury.

Due to the similarity between this device and the predicate device, the intended use, and the performance testing, it was determined that clinical data was not required and the simulated use study alone is acceptable for drawing the conclusions given below.

The testing above demonstrates that the device is safe and effective for its intended use and performs as well or better than the predicate device. As a safety accessory to the Harmac Huber Needle design, this device is designed to provide an additional level of safety during needle removal and to assist in compliance with current OSHA Safety Regulations. The implication of the device labeling is that this device will reduce the incidence of needle stick injuries when used according to the labeling in conjunction with a Harmac Huber Needle Infusion Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2002

Mr. Christopher Izzo
Senior Quality Assurance & Regulatory Affairs Engineer
Harmac Medical Products, Incorporated
2201 Bailey Avenue
Buffalo, New York 14211

Re: K021916
Trade/Device Name: Harmac Huber Needle Safety Device
Regulation Number: 880.5965, 880.5570 and 880.5440
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter, Hypodermic Single Lumen Needle and Intravascular Administration Set
Regulatory Class: II
Product Code: LJT, FMI and FPA
Dated: May 24, 2002
Received: June 11, 2002

Dear Mr. Moran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K021916

Device Name: Harmac Huber Needle Safety Device

Indications for Use:

The intended use of this device is for the removal of 90 degree winged infusion sets, manufactured by Harmac Medical Products and having a 1-1/2" needle or shorter, from implanted ports and the containment of the used needle until placed in an appropriate sharps container. When used in this manner this device is intended to aid in the prevention of needle stick injuries.

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021916

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use ___